



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,553	02/16/2001	Ming-Ming Zhou	2459-1-003 CIP	3124
23565	7590	01/15/2008		
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER LUCAS, ZACHARIAH	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 01/15/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/784,553	Applicant(s) ZHOU ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 9-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 1-6 and 9-36 are pending in the application.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 30, 2007 has been entered.
3. An After-Final amendment was submitted on September 18, 2006, in which amendment claims 5 and 6 were amended, and claims 7 and 8 were cancelled.
4. In the prior action, the Advisory action mailed on September 29, 2006, the After-Final amendment was entered, leaving claims 5 and 6 under consideration and rejected, and claims 1-4 and 9-36 withdrawn as to non-elected inventions.
5. Claims 5 and 6 are under consideration.

Claim Objections

(Prior Objection- Withdrawn) Claims 6 and 8 were objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. This rejection was withdrawn in the Advisory action of September 29, 2006.

Claim Rejections - 35 USC § 112

Art Unit: 1648

6. **(Prior Rejection- Withdrawn)** Claims 6 and 8 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection was withdrawn in the Advisory action of September 29, 2006.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Maintained)** Claims 5-8 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. As indicated in the Advisory action of September 2006, claims 7 and 8 were cancelled, and claims 5 and 6 were amended to read on specific PDZ peptides, the elected peptide of which is SEQ ID NO: 19.

The Applicant traverses the rejection on the bases that the present rejection is based on the 35 U.S.C. 112, first paragraph requirement that the application has not enabled those in the art to use the claimed invention without undue experimentation. The Applicant asserts that it was improper to make such a rejection without a corresponding rejection for lack of utility under 35 U.S.C. 101, and that because the Examiner appears to accept that there is a credible utility for the claimed invention, the enablement rejection should be withdrawn. This argument is not found persuasive.

First, it is noted that the Applicant characterizes the current rejection as a lack of utility rejection. This is not a correct characterization of the rejection. A rejection on the basis that an application has not enabled the use of a claimed invention has a different standard from the

Art Unit: 1648

rejection under 35 U.S.C. 101 for lack of utility. See e.g., MPEP 2107 IV. Because of the different standards, a rejection for lack of utility often necessitates a corresponding rejection for lack of enablement based because the application cannot teach how to use an invention that lacks utility under 35 U.S.C. 101. However, the MPEP also specifically points out that 35 U.S.C. 112, first paragraph “addresses matters other than those related to the question of whether or not an invention lacks utility,” and that “[t]he fact that an applicant has disclosed a specific utility for an invention and provided a credible basis supporting that specific utility does not provide a basis for concluding that the claims comply with all the requirements of 35 U.S.C. 112, first paragraph.” In the present case, the Applicant’s argument is based on the “logic” that because, where a rejection under 35 U.S.C. 101 for lack of utility is made, a corresponding rejection under 35 U.S.C. 112 should also be made for lack of enablement on the basis that those in the art have not been enabled to use the claimed invention. This argument, unsupported by any legal citations by the Applicant, is contrary to the law as described in the MPEP.

Applicant’s arguments also superficially relate several factors relating to the enablement requirement. However, the Applicant nowhere specifically addresses the concerns raised in the statement of the rejection in the prior actions, including the Advisory action of September 29, 2006. In particular, the Applicant nowhere provides any basis on which it could be found that those in the art would be enabled for the use of the claimed peptide for any purpose other than further study, even though it is accepted that the claimed peptide may eventually be found to have uses such that the claims meet the utility requirement.

For the reasons above, and the reasons of record, the rejection is maintained.

9. **(Prior Rejection- Withdrawn)** Claims 6 and 8 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for containing New Matter. This rejection was withdrawn in the Advisory action of September 29, 2006.

Claim Rejections - 35 USC § 102

10. **(Prior Rejection- Withdrawn)** Claims 6 and 8 were rejected under 35 U.S.C. 102(b) as anticipated by Denis and Green (Genes Dev 10(3): 261-71). This rejection was withdrawn in the Advisory action of September 29, 2006.

Conclusion

11. No claims are allowed.

12. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

Art Unit: 1648

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. Lucas/
Patent Examiner, AU 1648